IN THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next of Kin of RICHARD SMITH, Deceased,	)	Case #: 3:05-00444
	)	Judge Trauger
Plaintiff,	)	
-against-	)	
PFIZER INC., PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC, WARNER-LAMBERT COMPANY, WARNER-LAMBERT COMPANY LLC and JOHN DOE(S) 1-10,	)	
Defendants.	)	

STATEMENT OF PLAINTIFF'S EXPERT, MICHAEL TRIMBLE, M.D., AS TO SPECIFIC CAUSATION, PURSUANT TO LOCAL RULE 39.01(c)(6)(c)

[**Gabapentin was A Cause of Richard Smith's Suicide :** *continued from General Causation Statement*]

In addition to my opinion on general causation --- that Neurontin (Gabapentin) can cause depression and suicidality, I am here to explain and provide my opinion of how Mr. Richard's Smith's ingestion of Neurontin was a substantial factor in causing his suicide on May 13, 2004. My opinion is given with a reasonable degree of medical certainty.

Mr. Richard Smith shot himself in the early hours of the morning of May 13, 2004 having been on gabapentin only 65 days.

Turning our attention to the effect Gabapentin had on Mr. Smith, it is necessary to examine Mr. Smith's prior psychiatric and physical condition leading up to his death. Richard was 79 years old when he died. He was reasonably healthy for his age, but for a chronic orthopaedic pain syndrome related to his joints and back.

To form the bases of my opinion, I have reviewed materials, including medical records from Mr. Smith's treating doctors for several years prior to his death. I have reviewed

the deposition testimony from witnesses in this case[1] and a DVD which relates to Mr. Smith's personal family history. I have also reviewed the expert report prepared by Dr. Ron Maris, a suicidologist, who has also been retained by the Smith family's attorneys as an expert in this case.[2]

Mr. Smiths family history is significant that no one in his family history is known to have died by suicide and there is no known history of any family member with a psychiatric disorder.

While Mr. Smith had no family history or personal history of any psychiatric disorder, he did have a number of medical problems that caused him pain of various degree for a number of years. He had two knee replacements and a hip replacement in the 1990's, the first of which was in 1993. Going through the records there are some mentions that Mr. Smith was "depressed" because of pain. However, it is clear that this was not used in a psychiatric sense.

What do I mean? Well, a clinical diagnoses of depression – which is a risk factor for suicide – is far different than a transient feeling of low mood. In fact, there are indications in the medical records that although he was in a lot of pain, he was actually doing well. He was continuing with work, he was continuing to go to church and he was coping adequately up to the time of his death.

Following a history of increasing back pain, he had back surgery in 2002 and April 2003. During the time leading up to these surgeries, the medical records indicate the increased back pain had a negative effect on Mr. Smiths mood.

Prior to his second back surgery, his daughter was obviously concerned about him as she reported to Mr. Smith's doctor, Dr. Paul McCombs, that her father wished to die because of his pain and depression and there was a suggestion that he should go for psychiatric evaluation. This was on May 2, 2003.

We know, however, by October 13, 2003, after his second back surgery, Mr. Smith himself wrote in a copy along side the reference to his daughters comment. Lets take a look at the medical record from Neurosurgical Associates and Dr. Paul McCombs.

It says, "I was not aware that my daughter spoke to Dr. McCombs. I was in a lot of pain and medication and could have said something like this. I am healthy and still working some when possible."

[1] Trimble Depo. Transcript (September 2, 2009), at pp. 50-53 (referencing depositions).
[2] Trimble Depo. Transcript (September 2, 2008), at p.51 (referencing report of Maris, PhD).

21 April 03 OV: The patient returns to the office today in followup status post DLL four weeks ago. He is doing well ar the present time and is pleased with the results of his surgery to date. His wound is healing nicely and looks fine. I have advised him regarding the care of his back during this period of convalescence. He will use his discomfort as a guide for his activity. He will return to see me in four weeks in followup and further recommendations will depend on how he is doing at that time. PRM/jb

No letter.

4/28/03 pt c/o ↓BP leg pain being severe after going to church and out to lunch. He has a Medrol Dosepak that he will start on 4/29/03. He has taken 50 mg of Vicoff already today.

4/30/03 Pt continues w/ pain & is very concerned. 1:30 AM CMC CBC & diff ~~& cmp~~. Sed rate. Order faxed 342-3502

5/1/03 Pt notified per PK that scan is good as well as labs

5/2/03 Spoke w/ pts daughter. States pt. wishes he could die because of pain & depression. Advised to take pt. to ER for psych. eval ?H. PRM/PKH.

I was not aware that my daughter spoke to Dr. McCombs. I was in a lot of pain and medication and could have said something like this. I am healthy and still working some when possible.
R.S.

In the winter of 2003/2004, Mr. Smith described a return of pain and shooting pains down the legs, which caused him to seek further medical care and he was referred to Dr. Edward MacKey, who evaluated him for the possibility of a further operation. Prior to any surgical intervention the records indicate Dr. Mackey wanted to rule out any dementia. As you can see from the record of March 9, 2004, Dr. Mackey writes:

"His daughter raised the concern though about whether or not there are some other issues going on and we are going to go ahead and have him evaluated psychiatrically to make sure there is not a dementia type issue playing into this as well."

PATIENT NAME:	**SMITH, RICHARD**	DOS: **3/9/2004**
PATIENT NUMBER:	V118895	JOB: 336688
PROVIDER:	Edward S. Mackey, M.D.	
DOCUMENT TYPE:	Office Visit	
PRACTICE NAME:	Tennessee Orthopaedic Alliance	
CHART LOCATION:	2	

DOB: 1/04/25

Mr. Smith is seen back today. He reports knee pain and worsening bilateral leg pain, no weakness, but it is more radicular type pain. The pain has gotten to the point that he is getting around in a wheelchair. Again no focal deficits, but bilateral L5 and S1 radicular complaints. He is not sleeping well.

Bone scan shows photopenia in his lumbar spine which is not surprising. He shows AC joint arthritis. Myelogram shows probable non-union at 4-5 with a little bit of lateral recessed stenosis on the right at 4-5, but otherwise fairly unremarkable.

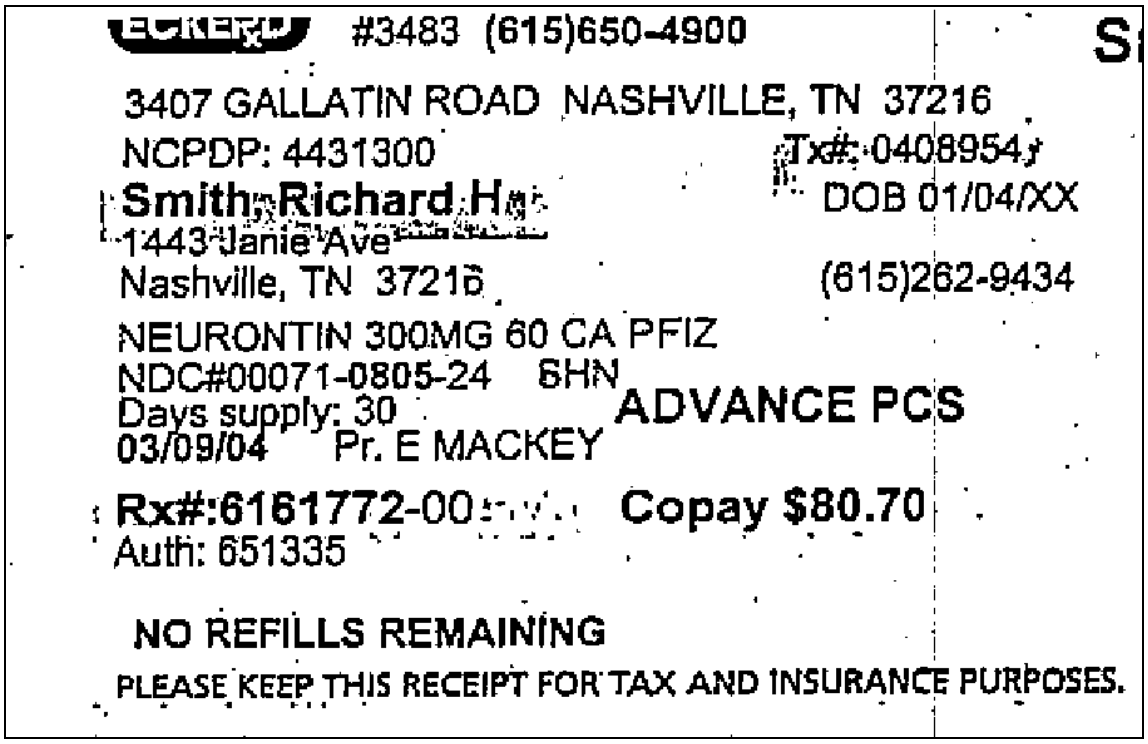
I told him that certainly we can consider surgery. We have discussed lumbar laminectomy and fusion in the past. We have discussed the use of pedicle screws and iliac crest bone graft. We discussed the use of bone morphogenetic protein. We are going to go ahead and make him an appointment to see Dr. Everette Howell. His daughter raised the concern though about whether or not there are some other issues going on and we are going to go ahead and have him evaluated psychiatrically to make sure there is not a dementia type issue playing into this as well.

Edward S. Mackey, M.D./bdc
Ov est. pt.
724.02

xc: Everette Howell, M.D.

James Cato, M.D.

We know from a review of an Eckerd Pharmacy prescription receipt that Mr. Smith filled a Neurontin prescription from Dr. Mackey on March 9, 2004. The prescription document reflects that he filled "Neurontin 300 mg", 60 pills, for a 30 day supply. So, I interpret this to mean a prescription of 2 pills per day for 30 days.



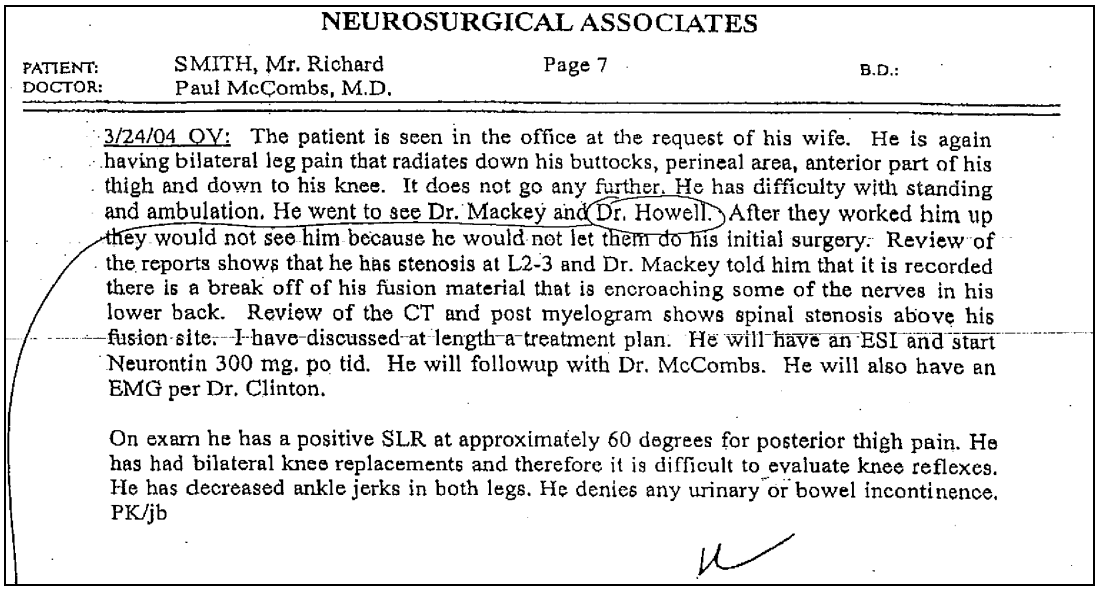
#3483 (615)650-4900

3407 GALLATIN ROAD NASHVILLE, TN 37216
NCPDP: 4431300 Tx#: 0408954
Smith, Richard H DOB 01/04/XX
1443 Janie Ave
Nashville, TN 37216 (615)262-9434
NEURONTIN 300MG 60 CA PFIZ
NDC#00071-0805-24 6HN
Days supply: 30 ADVANCE PCS
03/09/04 Pr. E MACKEY
Rx#:6161772-00 Copay $80.70
Auth: 651335

NO REFILLS REMAINING
PLEASE KEEP THIS RECEIPT FOR TAX AND INSURANCE PURPOSES.

We also have the benefit of a March 24, 2004 medical record from Mr. Smith's doctor at Neurosurgical Associates reflecting his prescription for Neurontin. It states, "I have discussed at length a treatment plan. He will have an ESI and start Neurontin 300 mg, p.o. tid. He will follow up with Dr. McCombs."

What does "p.o." mean? That means he is to take the Neurontin by mouth. What does "tid" mean? That means he is to take this dose 3 times daily. So, the total dose at that time was to be 900 milligrams per day.



NEUROSURGICAL ASSOCIATES

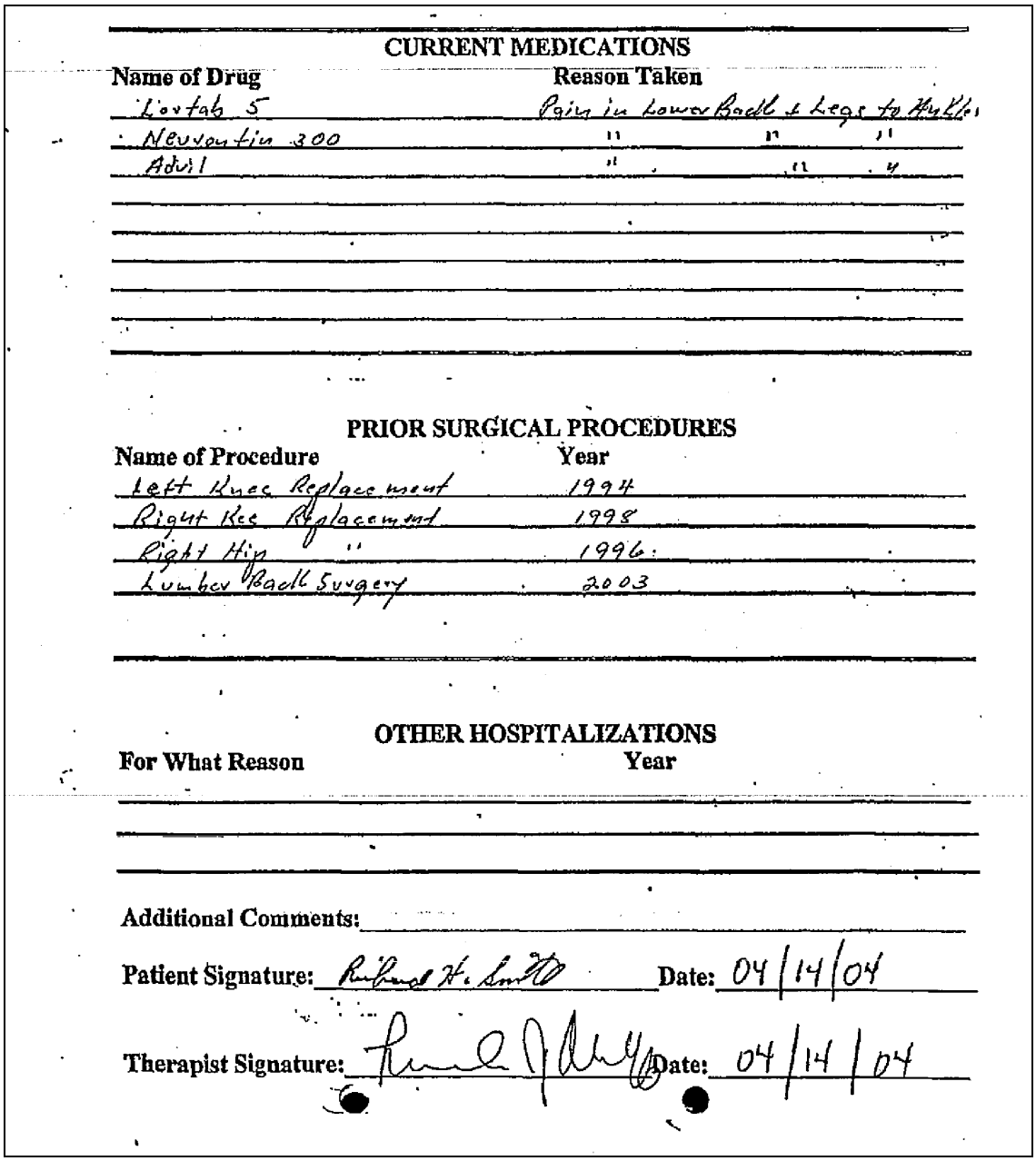
PATIENT: SMITH, Mr. Richard Page 7 B.D.:
DOCTOR: Paul McCombs, M.D.

3/24/04 OV: The patient is seen in the office at the request of his wife. He is again having bilateral leg pain that radiates down his buttocks, perineal area, anterior part of his thigh and down to his knee. It does not go any further. He has difficulty with standing and ambulation. He went to see Dr. Mackey and Dr. Howell. After they worked him up they would not see him because he would not let them do his initial surgery. Review of the reports shows that he has stenosis at L2-3 and Dr. Mackey told him that it is recorded there is a break off of his fusion material that is encroaching some of the nerves in his lower back. Review of the CT and post myelogram shows spinal stenosis above his fusion site. I have discussed at length a treatment plan. He will have an ESI and start Neurontin 300 mg. po tid. He will followup with Dr. McCombs. He will also have an EMG per Dr. Clinton.

On exam he has a positive SLR at approximately 60 degrees for posterior thigh pain. He has had bilateral knee replacements and therefore it is difficult to evaluate knee reflexes. He has decreased ankle jerks in both legs. He denies any urinary or bowel incontinence. PK/jb

In addition to the prescription, my understanding from witness deposition testimony is that Mr. Smith was given several additional pills through doctor samples. What does this mean? This means that Mr. Smith received Neurontin directly from the doctor's office as opposed to having to travel to the pharmacy and fill a prescription.

On April 14, 2004,Mr. Smith began physical therapy at the UMC-Pain Center, in Nashville. He indicated he was taking his Neurontin, along with Lortab and Advil. He also indicated he had been treated or diagnosed with "depression, anxiety".



CURRENT MEDICATIONS

Name of Drug	Reason Taken
Lortab 5	Pain in Lower Back & Legs to Knees
Neurontin 300	" " "
Advil	" " "

PRIOR SURGICAL PROCEDURES

Name of Procedure	Year
Left Knee Replacement	1994
Right Knee Replacement	1998
Right Hip "	1996
Lumbar Back Surgery	2003

OTHER HOSPITALIZATIONS

For What Reason	Year

Additional Comments:

Patient Signature: Richard H. Smith Date: 04/14/04

Therapist Signature: [signature] Date: 04/14/04

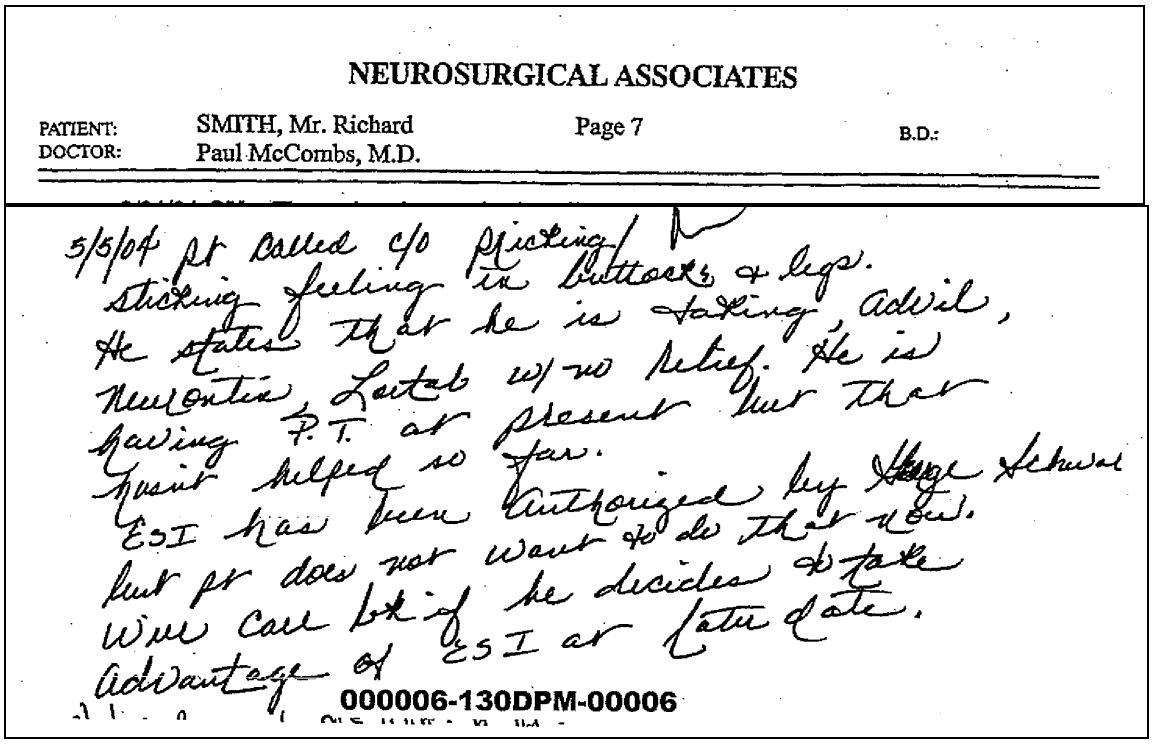
UMC Pain Center- Physical Therapy Services Pg 4 of 7
112 Babb Drive Lebanon, TN 37087
Phone 615-547-0410 FAX 615-547-0417 Medical History

Patient Name: Richard "Smith Age: 79 Physician: Paul McCombs

If you have ever been treated or diagnosed with the following, please mark and provide additional information in the spaces provided.

__Allergies including medications CIPRO
__Diabetes; diet, medication, or insulin controlled
__Cardiac (heart) conditions including
blood pressure, pacemaker, vascular
disorders, history of rheumatic fever
__Arthritis; what type?
__Pulmonary (lung) disease including COPD
tuberculosis, bronchitis, asthma
__Intestinal disorders including cholitis,
diverticulitis, hernia, gall bladder disease,
ulcers, irritable bowel syndrome
__Liver disease
__Seizure disorders including epilepsy or convulsions
__CVA (stroke) or paralysis
__Cancer, if yes what type?
__Previous orthopedic injuries, (B) Knee R. Replace (R) THR
broken bones, sprains/strains
__Problems with eyes, nose, ears, throat
__Thyroid or gland disorders
__Skin disease/disorders
__Alcohol/Drug Dependency
__Depression, anxiety, and other
mental illness

Mr. Smith's use of Neurontin is also reflected in a medical record of May 5, 2004, just 8 days before he committed suicide. On May 5, 2004, Mr. Smith called Dr. McCombs office whose record indicates "He states that he is taking advil, Neurontin, lortab "with no relief."



NEUROSURGICAL ASSOCIATES

PATIENT: SMITH, Mr. Richard Page 7 B.D.:
DOCTOR: Paul McCombs, M.D.

5/5/04 pt called c/o sticking/ stabbing feeling in buttocks & legs. He states that he is taking advil, Neurontin, Lortab w/ no relief. He is having P.T. at present but that hasn't helped so far. ESI has been authorized by Judge Schwab but pt does not want to do that now. Will call back if he decides to take advantage of ESI at later date.

000006-130DPM-00006

There is evidence that Mr. Smith considered that the gabapentin was affecting him mentally. He told his wife that he considered there was something wrong with his mind and that he did not think like he used to. He told his son-in-law that he felt "loopy", and that gabapentin made him feel weird.

In my capacity as a scientist, medical doctor, and expert in this case, I have considered Mr. Smith's social and medical history to account for things in Mr. Smith's life that could have led him to commit suicide. Suicide is a very rare event that has been substantially studied in the medical community. While suicide is a devastating end point of psychopathology, there are a number of predictors of people who are most at risk of suicidal behavior. Those at higher risk are people who live alone, those with alcohol or drug dependence, those with known severe psychiatric disorders, such as a major depressive disorder or schizophrenia, and those who have had previous attempts to harm themselves. Each of these risk factors exponentially increase the risk one may die by suicide and the absence of these risk factors predictably indicate it is not likely one will die by suicide.

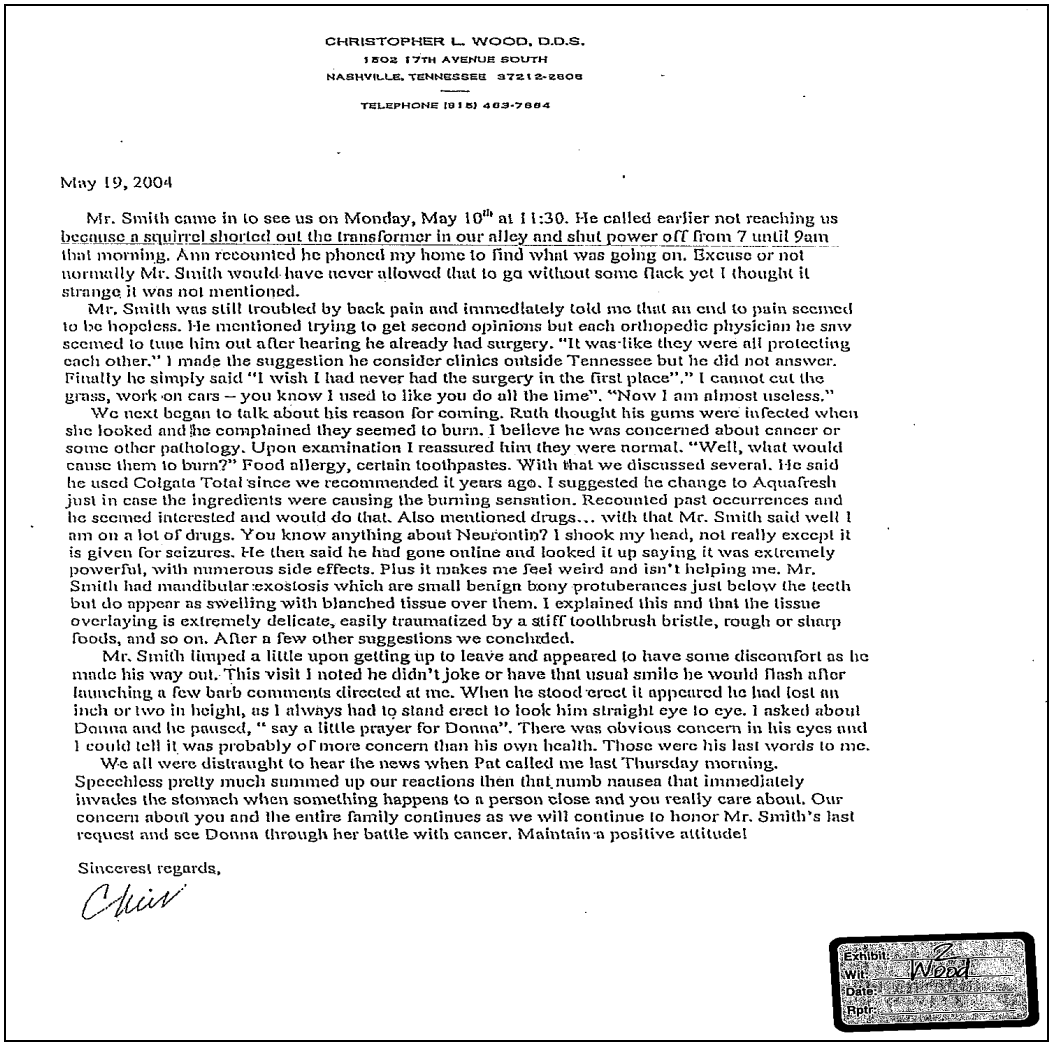
None of these known risk factors for suicide are present in the past history of Mr. Smith. He grew up in a secure, parental background; there is no known history of any psychiatric disorder; he has demonstrated a steady work record with a single employer for many years, and he also had an alternative additional noble career as a church minister.

It is my opinion that absent a chemical change in Mr. Smith's brain by a pharmaceutical agent, it was not likely at all Mr. Smith would have committed his suicide.

Once Mr. Smith began taking Gabapentin, it is my opinion that his mental state altered. Mr. Smith's altered mental state was consistent with the way I have earlier described how Gabapentin can cause depression and suicidality.

There are additional points in the evidence I must bring to your attention. Following the start of taking Gabapentin, Mr. Smith's wife has testified under oath that Mr. Smith expressed suicidal ideation when he inquired; "honey, you think God would forgive me if I just do away with myself. "

In addition, on May 10, 2004, just a few days before his suicide, Mr. Smith told his dentist, Dr. Wood, that Gabapentin made him "feel weird" and that it was not helping him. Mrs. Smith's own discussion about his behavior in the few weeks while he was on gabapentin and before he killed himself was that he believed there was something wrong with his mind.



CHRISTOPHER L. WOOD, D.D.S.
1502 17TH AVENUE SOUTH
NASHVILLE, TENNESSEE 37212-2606
TELEPHONE (615) 463-7664

May 19, 2004

Mr. Smith came in to see us on Monday, May 10th at 11:30. He called earlier not reaching us because a squirrel shorted out the transformer in our alley and shut power off from 7 until 9am that morning. Ann recounted he phoned my home to find what was going on. Excuse or not normally Mr. Smith would have never allowed that to go without some flack yet I thought it strange it was not mentioned.

Mr. Smith was still troubled by back pain and immediately told me that an end to pain seemed to be hopeless. He mentioned trying to get second opinions but each orthopedic physician he saw seemed to tune him out after hearing he already had surgery. "It was like they were all protecting each other." I made the suggestion he consider clinics outside Tennessee but he did not answer. Finally he simply said "I wish I had never had the surgery in the first place"." I cannot cut the grass, work on cars – you know I used to like you do all the time". "Now I am almost useless."

We next began to talk about his reason for coming. Ruth thought his gums were infected when she looked and he complained they seemed to burn. I believe he was concerned about cancer or some other pathology. Upon examination I reassured him they were normal. "Well, what would cause them to burn?" Food allergy, certain toothpastes. With that we discussed several. He said he used Colgate Total since we recommended it years ago. I suggested he change to Aquafresh just in case the ingredients were causing the burning sensation. Recounted past occurrences and he seemed interested and would do that. Also mentioned drugs… with that Mr. Smith said well I am on a lot of drugs. You know anything about Neurontin? I shook my head, not really except it is given for seizures. He then said he had gone online and looked it up saying it was extremely powerful, with numerous side effects. Plus it makes me feel weird and isn't helping me. Mr. Smith had mandibular exostosis which are small benign bony protuberances just below the teeth but do appear as swelling with blanched tissue over them. I explained this and that the tissue overlaying is extremely delicate, easily traumatized by a stiff toothbrush bristle, rough or sharp foods, and so on. After a few other suggestions we concluded.

Mr. Smith limped a little upon getting up to leave and appeared to have some discomfort as he made his way out. This visit I noted he didn't joke or have that usual smile he would flash after launching a few barb comments directed at me. When he stood erect it appeared he had lost an inch or two in height, as I always had to stand erect to look him straight eye to eye. I asked about Donna and he paused, " say a little prayer for Donna". There was obvious concern in his eyes and I could tell it was probably of more concern than his own health. Those were his last words to me.

We all were distraught to hear the news when Pat called me last Thursday morning. Speechless pretty much summed up our reactions then that numb nausea that immediately invades the stomach when something happens to a person close and you really care about. Our concern about you and the entire family continues as we will continue to honor Mr. Smith's last request and see Donna through her battle with cancer. Maintain a positive attitude!

Sincerest regards,

Chris

Exhibit: 2
Wit: Wood
Date:
Rptr:

Mr. Smith had a very strong protection from suicide. Mr. Smith was a devout Churchman, with strong religious beliefs leading to a life time career of helping others, counseling others and working assiduously for the church. One of the protective factors that is associated with less suicidal behavior is strong religious beliefs. Thus, suicidal ideation and religious beliefs are inversely correlated. Given Mr. Smith's strong religious affiliation it is my opinion on the balance of probabilities that but for the ingestion of Gabapentin it is very unlikely Mr. Smith would have died by suicide.

Finally, I would like to point out to you that Mr. Smith's use of Neurontin – only a little over 2 months --- is consistent with the U.S. FDA's analysis for increased risk of suicidal behavior with anticonvulsant drugs. The FDA observed that increased risk for suicidal behavior continued through at least 24 weeks, or 6 months. Mr. Smith's use of Neurontin falls squarely within the time period studied.

Therefore, in the absence of recognizable psychiatric disorder, the spontaneous and impulsive nature of his suicidal act requires explanation. Gabapentin is associated with changes of brain chemistry which, I find with a reasonable degree of scientific and medical probability, leads to impulsive and suicidal acts. It is therefore my opinion that it is more likely than not the Gabapentin was a substantial factor in Mr. Smith committing suicide.